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(54) Title: A CLOSURE DEVICE FOR AN INTESTINAL OPENING		
(57) Abstract		
<p>A closure device for an intestinal opening comprises a collapsible thin-walled container (14). The open end of the container is releasably retained in sealing relationship with the intestinal opening by means of a retaining member (19). The intestinal opening is closed by means of a closure member (16), and the container (14) is located mainly inside the closure member in a collapsed condition. When the closure member (16) has been released the end of the container (14) opposite to the open end may be retracted so as to extend part of the container outside from the intestinal opening, whereby body waste products may be discharged from the intestinal opening into the container part extending therefrom.</p>		

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A CLOSURE DEVICE FOR AN INTESTINAL OPENING

The present invention relates to a closure device of the disposable type for closing an intestinal opening, for example an artificial or an incontinent natural opening.

- 5 European patent application published under No. 0 188 376 discloses a stopper-like closure for an intestinal opening. The known closure comprises an elastic, expandable body, which is held in a compressed state prior to insertion, and which may be released so that it is allowed to expand within the opening after insertion. The known
10 closure also comprises a base plate, which may be adhered to the outer skin surface around the intestinal opening. The base plate comprises a coupling ring which may cooperate with a radially extending plate member of the stopper-like body so as to retain the stopper in position. On removal of the plug a colostomy bag may be applied to
15 the same body plate, and after evacuation the colostomy bag is removed and a new plug-like body is applied.

Such an evacuation operation also involves washing of the area around the intestinal opening for removing residual visceral contents and/or replacement of the base plate. Furthermore, the device according to
20 the prior art is not well adapted for use when the secretion is liquid, such as in cases of colostomy with diarrhoea or ileostomy.

The present invention provides a closure device of the above type which substantially facilitates the evacuation of intestinal contents.

- 25 Thus, the present invention provides a closure device for an intestinal opening and comprising a collapsible thin-walled container having an open first end defining a container inlet, a retaining member connected to the open end of the container for releasably retaining said open end in sealing relationship with the intestinal
30 opening, a closure member for closing the intestinal opening with the container located mainly inside the closure member in a collapsed condition, a second end of the container opposite to the open first end being retractable when the closure member has been opened so as

to extend part of the container outside from the intestinal opening, whereby body waste products may be discharged from the intestinal opening into the container part extending therefrom.

- When the open end of the container has been sealingly connected so as
- 5 to communicate with the intestinal opening or stomy, and the closure member has been mounted with the container in a collapsed condition, the closure device according to the invention may be worn by the user with much less discomfort than a conventional stomy bag. When a certain amount of visceral contents have collected inside the intestine it may be discharged or evacuated simply by opening the closure member and extending at least part of the container outside from the intestinal opening. When the visceral contents have been discharged into the retainer, the retaining member may be released and discarded together with its contents, whereafter a new closure device may be
- 10 mounted.
- 15

- The retaining member may be adapted to releasably fasten the open end of the container to the outer surface of the body of the user around the intestinal opening or stomy. However, in the preferred embodiment, the retaining member comprises a radially extensible part
- 20 defining the container inlet and being adapted to be inserted into the intestinal opening and to be extended inside thereof so as to retain the container inlet therein. It may then be avoided that the faecal matter comes into contact with the outer skin surface of the user, whereby a closure device according to the invention may be
- 25 replaced by another one without the necessity of washing the body of the user around the intestinal opening.

- The radially extensible part may be of any suitable structure. As an example, the radially extensible part may be a tapered tubular part movable from its initially tapered condition into a radially extended
- 30 funnel-shaped condition. The tapered tubular part may easily be inserted into the intestinal opening, and thereafter it may be moved into its funnel-shaped condition like an umbrella which is being opened. The funnel shape serves to retain the tubular part or retaining member inside the intestinal opening. Alternatively, the radially extensible part may comprise an elastic ring which may be inserted
- 35

into the intestinal opening in a compressed, preferably elongated condition. The ring may be retained in its compressed condition by means which are dissolved or otherwise inactivated by the humidity and/or temperature within the intestine.

- 5 The said second end of the container may be connected to the closure member, whereby the container part is automatically retracted when the closure member is removed from the intestinal opening so that discharge of faecal matter may start as soon as the closure member has been removed.
- 10 The closure member may be of any type which is able to house the collapsed container and to seal the intestinal opening, possibly in continuation with the retaining member. As an example, the closure device may comprise an annular fastening member adapted to be adhered to the outer skin area around the intestinal opening, the closure member comprising a cap member engaging with the fastening member in a closed position of the closure member. If the radially extensible retaining member may form an efficient seal against the inner intestinal wall, the closure member need not seal the intestinal opening, but should at least be able to retain the container in a collapsed
- 15 position. In that case faecal matter may to some extent penetrate into the opening through the container inlet. However, in the preferred embodiment of the closure device, the closure member comprises a stopper member to be inserted in the intestinal opening in the closed position of the closure member, whereby faecal matter is prevented
- 20 from penetrating into the intestine, until the closure member with the said stopper member has been released and removed from the intestinal opening.
- 25

- The stopper member may be combined with the above-mentioned cap member which may, for example, form a flange at the outer end of the
- 30 stopper member, which may be fastened to and extend axially from the inside of the cap member. The engagement between the cap member and the annular fastening member which is adhered to the outer skin of the user, may then prevent the stopper member from being expelled from the intestinal opening.

The stopper member is preferably made from an elastic material so that it may seal against the inner intestinal wall. The insertion of the stopper member may be facilitated by using a stopper member of the type which is expandible when exposed to heat and/or moisture. As 5 an example, the stopper member may be of the type disclosed in the above-mentioned published European patent application.

In another embodiment according to the present invention the collapsible container is wrapped around a stopper member consisting of foam and which can be squeezed through the intestinal opening, and by 10 expanding again inside the body will expand part of the collapsible container located inside the body.

The container must be made from a material allowing the container to attain a collapsed condition. As an example, the container may be made from any plastic film material which is conventionally used for 15 producing stomy bags. In the preferred embodiment, however, the container is made from a stretchable material, so that the container may be housed in a relatively small space in its collapsed condition. As an example, the container may be made from polyurethane or latex, or any other material from which condoms are conventionally produced.

20 The above-mentioned annular fastening member, which is adapted to be adhered to an outer skin area around the intestinal opening, may be provided with fastening means of the Velcro or adhesive type, and the cap member may be replaced by a plate member having similar fastening means for cooperating with the Velcro or adhesive fastening means on

25 the annular fastening member. In such case, the collapsed container may be clamped between the plate member and the annular fastening member. Alternatively, a special chamber may be defined in the closure member for housing the collapsed container when the closure member is in its closed position.

30 The closure member advantageously comprises a gas filter communicating with the inner space of the container and, consequently, with the inner space of the intestine so that intestinal gases may escape through the filter when the closure member is in its closed position. The container may be closed at its said second end so that it has a

condom-like or bag-like shape. Alternatively, the container may be defined by a tubular member having first and second opposite open ends, and the second open end may then be tightly connected to the inner side of the closure member, for example around a gas filter 5 mounted in the closure member.

The invention will now be further described with reference to the drawings, wherein

Fig. 1 is a sectional view of a first embodiment of the closure device according to the invention which has just been mounted in an 10 intestinal opening or stomy and with the retaining member in its collapsed condition,

Fig. 2 is the same as Fig. 1, but with the retaining member in its expanded condition,

Figs. 3 and 4 illustrate two different steps of discharging faecal 15 matter and removing the closing device,

Fig. 5 is a sectional view of a second embodiment of the closure device according to the invention, which has just been mounted with the retaining member and the stopper member in a collapsed condition,

Fig. 6 is the same as Fig. 5, but with the retaining member and the 20 stopper member in a expanded condition,

Fig. 7 illustrates the closing device shown in Figs. 5 and 6 during the process of discharging faecal matter from the intestine,

Fig. 8 is an exploded view of a third embodiment of the closure device according to the invention, and

25 Fig. 9 is a sectional view of a fourth embodiment of the closure device according to the invention.

The closure device shown in Figs. 1-4 comprises a mounting ring 10 which by means of an adhesive layer 11 may be fastened to the skin surface 12 surrounding an intestinal opening or a stomy 13. The 30 closure device further comprises a collapsible tubular container 14 having its outer end connected to the inner side of a radially extending flange 15 of a closure member 16. The closure member 16 also comprises an axially extending stopper member 17 extending axially into the inner space of the tubular container 14. The inner open end 35 of the container 14 is fastened to a ring member 18 forming part of an expandible retaining member 19.

When the mounting ring 10 has been adhered to the skin surface 12 around the stomy 13 a unit comprising the collapsed retaining member 19 and the closure member 16 with the stopper member 17 received in the ring member 18 is inserted into the stomy or intestinal opening 13 as shown in Fig. 1, and the closure member 16 is releasably fastened to the mounting ring 10 by means of complementary, inter-engaging, releasable fastening means 20, which may, for example be thread-like members.

The retaining member 19 may now be moved to an expanded position like an umbrella as shown in Fig. 2. Movement of the retaining member 19 from the collapsed position shown in Fig. 1 to the expanded position shown in Fig. 2 may be caused by mechanical activation, or by the moisture and/or temperature conditions within the intestine 21. As an example, the retaining member 19 may be biased towards its expanded position and may be retained in its collapsed position by a surrounding string or wrapping (not shown) which is dissolved when inserted into the intestine 21.

Faecal matter 22 may now be collected within the intestine 21 adjacent to the closure device. When the user wants to discharge the intestine contents or faecal matter 22, the closure member 16 is released from the mounting ring 10 and withdrawn so as to retract the collapsible container 14 from its collapsed condition shown in Figs. 1 and 2. The faecal matter 22 may now be discharged from the intestine 21 so that it is totally contained within the container 14, whereafter the retaining member 19, which may now be returned to its collapsed condition, is withdrawn from the intestine. Now, the closure device with the faecal matter 22 contained therein (Fig. 4) may be discarded, and a new closure device may be mounted as shown in Fig. 1.

In the embodiments shown in Figs. 5-7, the stopper member 17 is made from a elastically compressible material, and the retaining member 19 is an elastically compressible ring. The radially compressed stopper member and retaining ring 19 is enclosed by a retaining film 23 which may be dissolved or disintegrated when inserted into the intestine

21. A storage chamber 24 for housing the collapsed container or folded bag 14 is formed on the inner side of the flange 15, and the open inner end of the container is connected to the retaining ring 19.
- 5 When the compressed stopper member 17 has been inserted into the stomy 13 and the flange 15 has been fastened to the mounting ring 10 by means of the releasable fastening means or thread-like members 20 as shown in Fig. 5, the retaining film 23 will be exposed to the conditions within the intestine 21, whereby it is dissolved or otherwise disintegrated. This causes the stopper member 17 and the retaining ring 19 to expand radially as shown in Fig. 6. Now, the intestine contents or faecal matter 22 may collect within the intestine 21 adjacent to the stopper 17 as shown in Fig. 6. When the user wants to discharge the collected faecal matter 22 from the intestine 21, the 10 user releases the flange 15 from the mounting ring 10 and retracts the stopper 17 from the stomy 13 whereby the collapsible container 14 is axially extended as shown in Fig. 7. The faecal matter 22 may now be transferred from the intestine into the container 14 outside the intestinal opening 13, whereafter the retaining ring 19 may be withdrawn from the intestine 21, and a new closing member may be mounted 15 as shown in Fig. 5.
- 20

Fig. 8 shows an embodiment in which the outside of the mounting ring 10 is provided with fastening means 25 of the Velcro type. The inner free end of the collapsible container 14 is provided with a radial flange 26 which is also provided with Velcro fastening means so that the flange 26 may be releasably fastened to the mounting ring 10. The outer end of the container 14 is closed by a closure plate 27 which is provided with fastening means 28 of the Velcro type radially outside the container 14. The closure device illustrated in Fig. 8 25 may be mounted by mounting the flange 26 of the container 14 to the mounting ring 10, whereafter the closure plate 27 may be pressed into engagement with the mounting ring 10, so that the fastening means 25 and 28 may cooperate to releasably retain the closure plate 27 in a 30 closed position.

- When faecal matter has collected within the intestine 21, the closure plate 27 may be released from the mounting plate 10 so as to axially extend the collapsible container 14. When the faecal matter has been transferred from the intestine 21 into the container 14, the flange 5 26 may be released from the mounting plate 10, whereafter the device is discarded and a new closing device may be mounted.

The container 14 may be made from any collapsible material, such as a film from any suitable plastic material. In the preferred embodiment, however, the collapsible container is made from a stretchable material, such as polyurethane or latex. In the embodiment shown in Figs. 10 1-4, the stopper member 17 may be made from rubber or plastic which may cooperate with the ring member 18 so as to form a seal, and the adhesive 11 may be of any type conventionally used in connection with stomy bags. In the embodiment shown in Figs. 5-7, the stopper member 15 17 and the retaining film or cover may be of any of the types disclosed in European patent application published under No. 0 188 376, which is included herein by reference. The retaining ring 19 may be of a similar material as the expandible stopper member 17. The closure member 16 may include a gas passage containing a deodorizing 20 filter member (not shown) for allowing intestinal gas to escape to the atmosphere in the closed position of the closure device.

- Fig. 9 shows an embodiment of the closure device according to the invention having a stopper member 17 which is made of a resilient foam. Prior to mounting a part of the collapsible container 14 is 25 wrapped around the stopper member 17 which can subsequently be squeezed through the intestinal opening 13. After being squeezed through the opening 13 the stopper member 17 will again expand substantially to its original shape, and thereby expand the collapsible container 14.
- 30 It should be understood that various amendments and modifications of the embodiments described above could be made within the scope of the present invention.

CLAIMS

1. A closure device for an intestinal opening and comprising
a collapsible thin-walled container having an open first end
defining a container inlet,
5 a retaining member connected to the open end of the container
for releasably retaining said open end in sealing relationship with
the intestinal opening,
 a closure member for closing the intestinal opening with the
container located mainly inside the closure member in a collapsed
10 condition,
 a second end of the container opposite to the open first end
being retractable when the closure member has been opened so as to
extend part of the container outside from the intestinal opening,
whereby body waste products may be discharged from the intestinal
15 opening into the container part extending therefrom.
2. A closure device according to claim 1, wherein the retaining
member comprises a radially extensible part defining the container
inlet and being adapted to be inserted into the intestinal opening
and to be extended inside thereof so as to retain the container inlet
20 therein.
3. A closure device according to claim 2, wherein the radially ex-
tensible part is a tapered tubular part movable from its initially
tapered condition into a radially extended funnel-shaped condition.
4. A closure device according to any of the claims 1-3, wherein said
25 second end of the container is connected to the closure member,
whereby the container part is retracted when the closure member is
removed from the intestinal opening.
5. A closure device according to any of the claims 1-4, further
comprising an annular fastening member adapted to be adhered to an
30 outer skin area around the intestinal opening, the closure member
comprising a cap member engaging with the fastening member in a
closed position of the closure member.

6. A closure device according to any of the claims 1-5, wherein the closure member comprises a stopper member to be inserted in the intestinal opening in the closed position of the closure member.
7. A closure device according to claim 5 and 6, wherein the stopper member is fastened to and extends axially from the inside of the cap member.
8. A closure device according to claim 6 or 7, wherein the stopper member is of a type which is expandible when exposed to heat and/or moisture.
- 10 9. A closure device according to claim 6 or 7, wherein the stopper member is of a type which is compressible, so that it can be squeezed through the intestinal opening and expand inside the body.
10. A closure device according to claim 9, wherein the container is made from polyurethane or latex.
- 15 11. A closure device according to any of the claims 1-10, wherein said container part is housed in a chamber defined in the closure member, when the closure member is in its closed position.
12. A closure device according to any of the claims 1-11, wherein the closure member comprises a gas filter communicating with an inner space of the container.
- 20 13. A closure device according to any of the claims 1-12, wherein the container is defined by a tubular member having first and second opposite open ends, the second open end being tightly connected to the inner side of the closure member.

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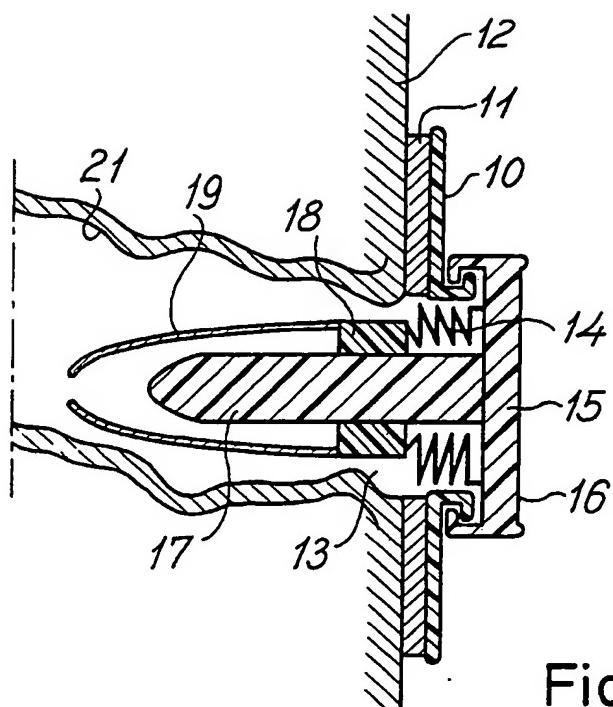


Fig. 1

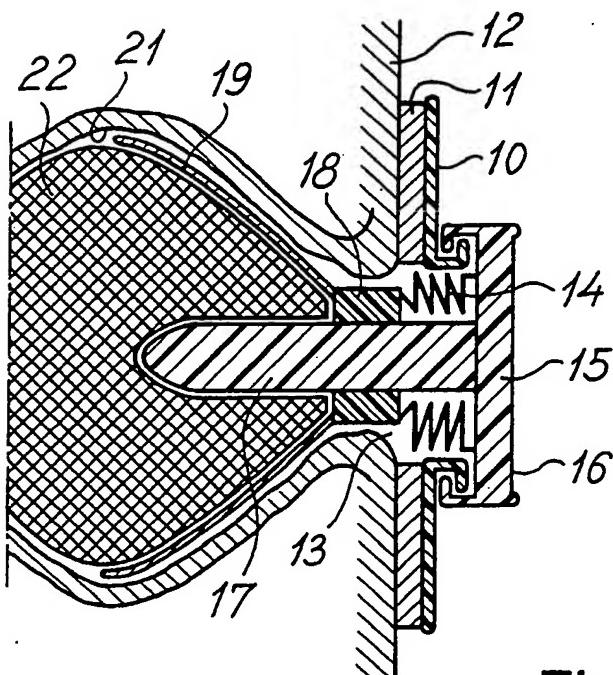


Fig. 2

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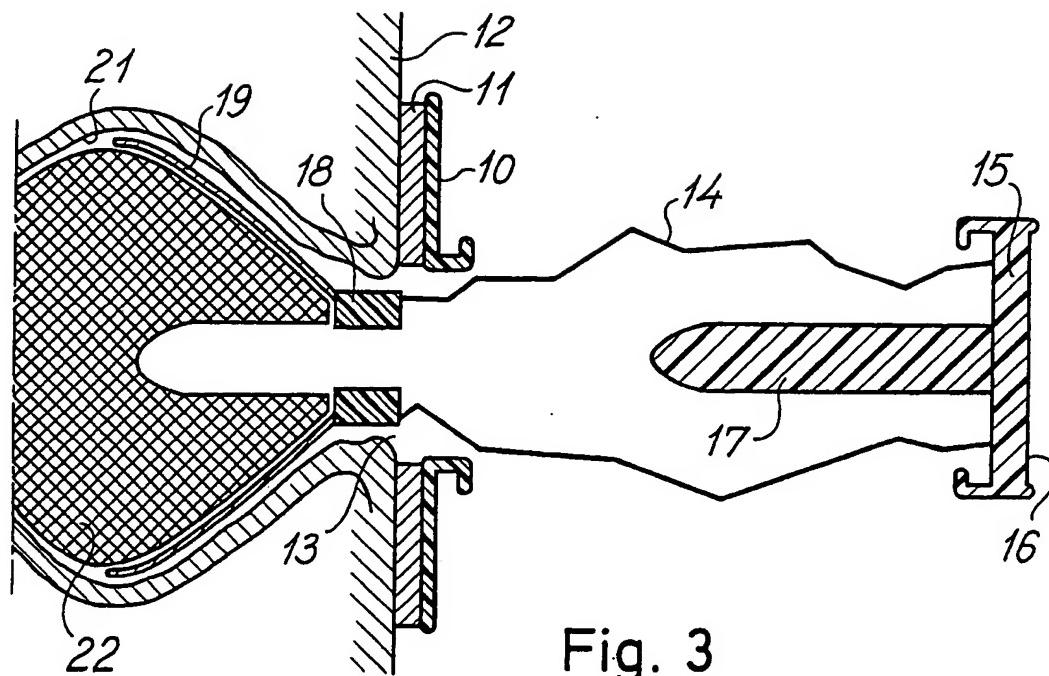


Fig. 3

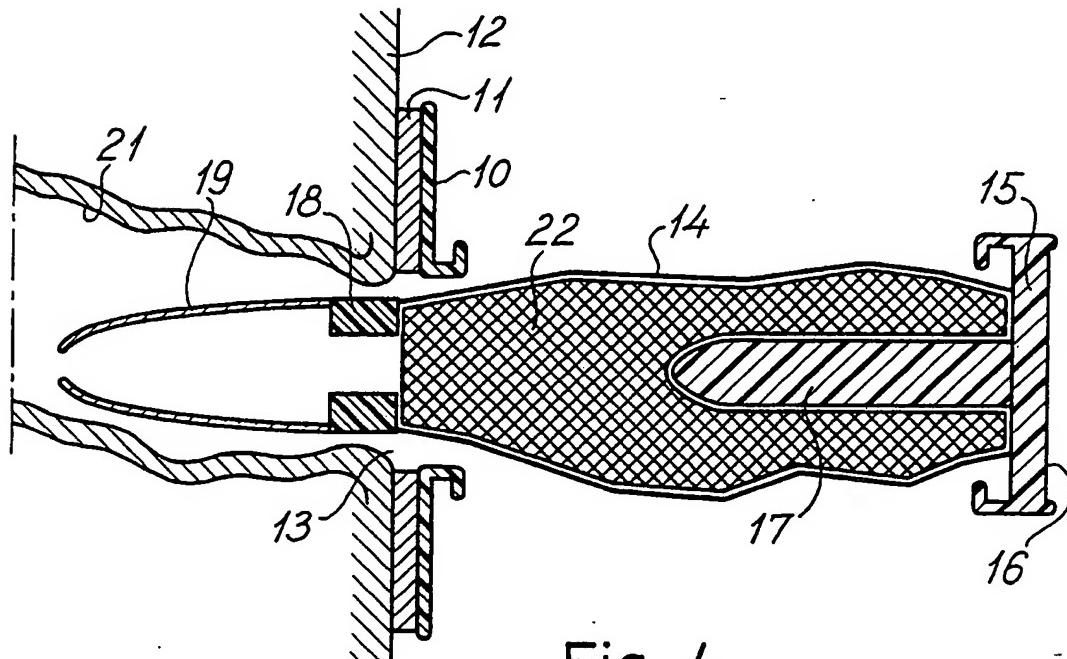


Fig. 4

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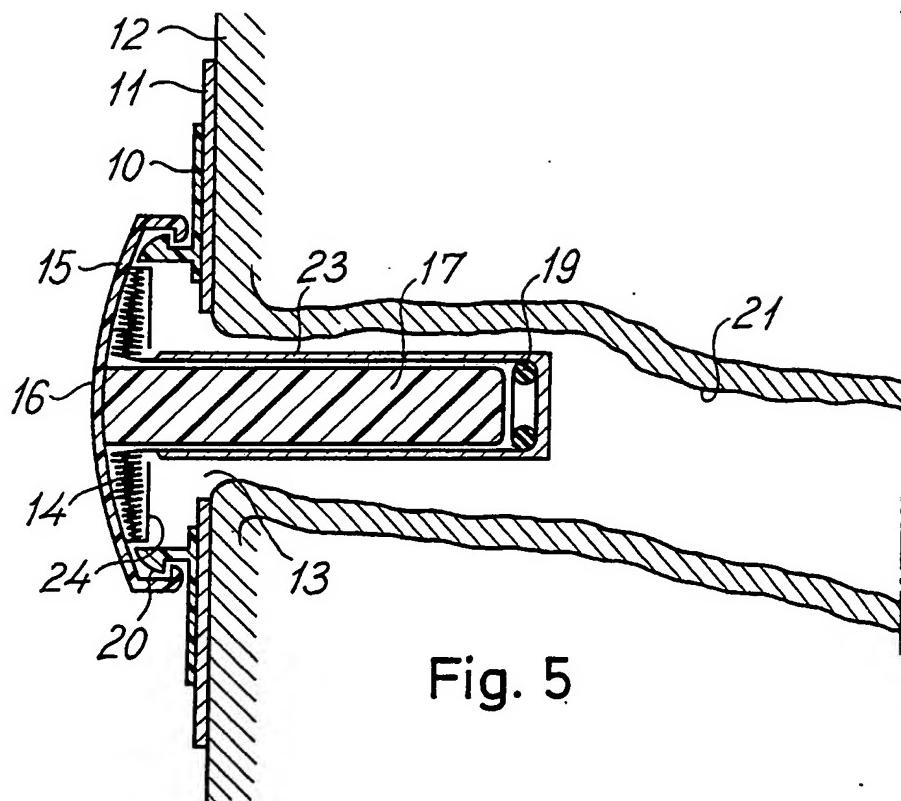


Fig. 5

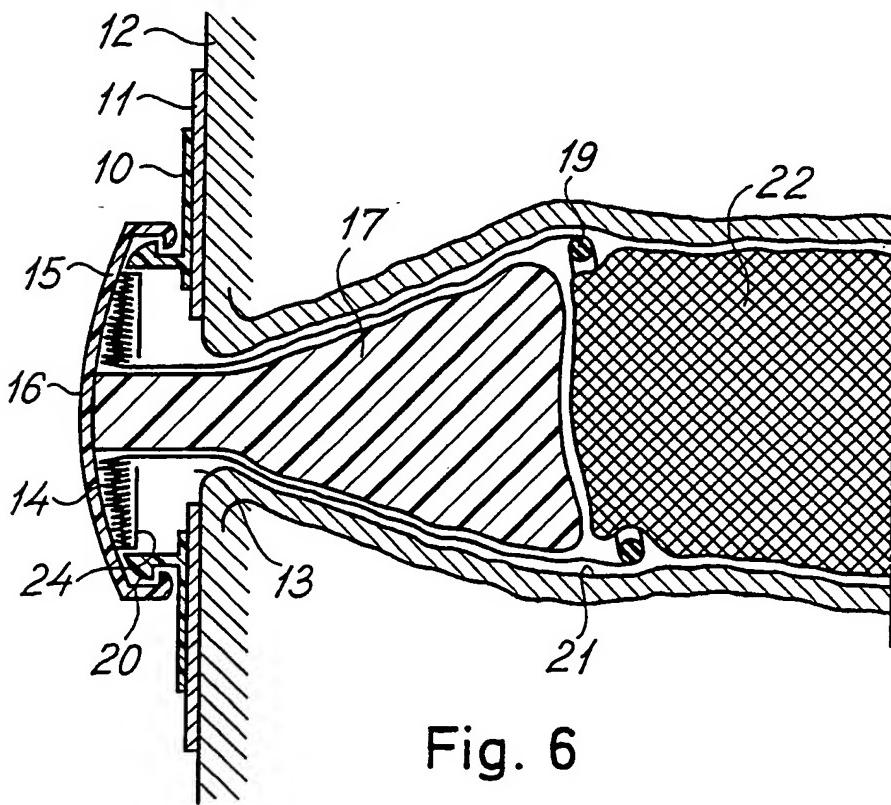


Fig. 6

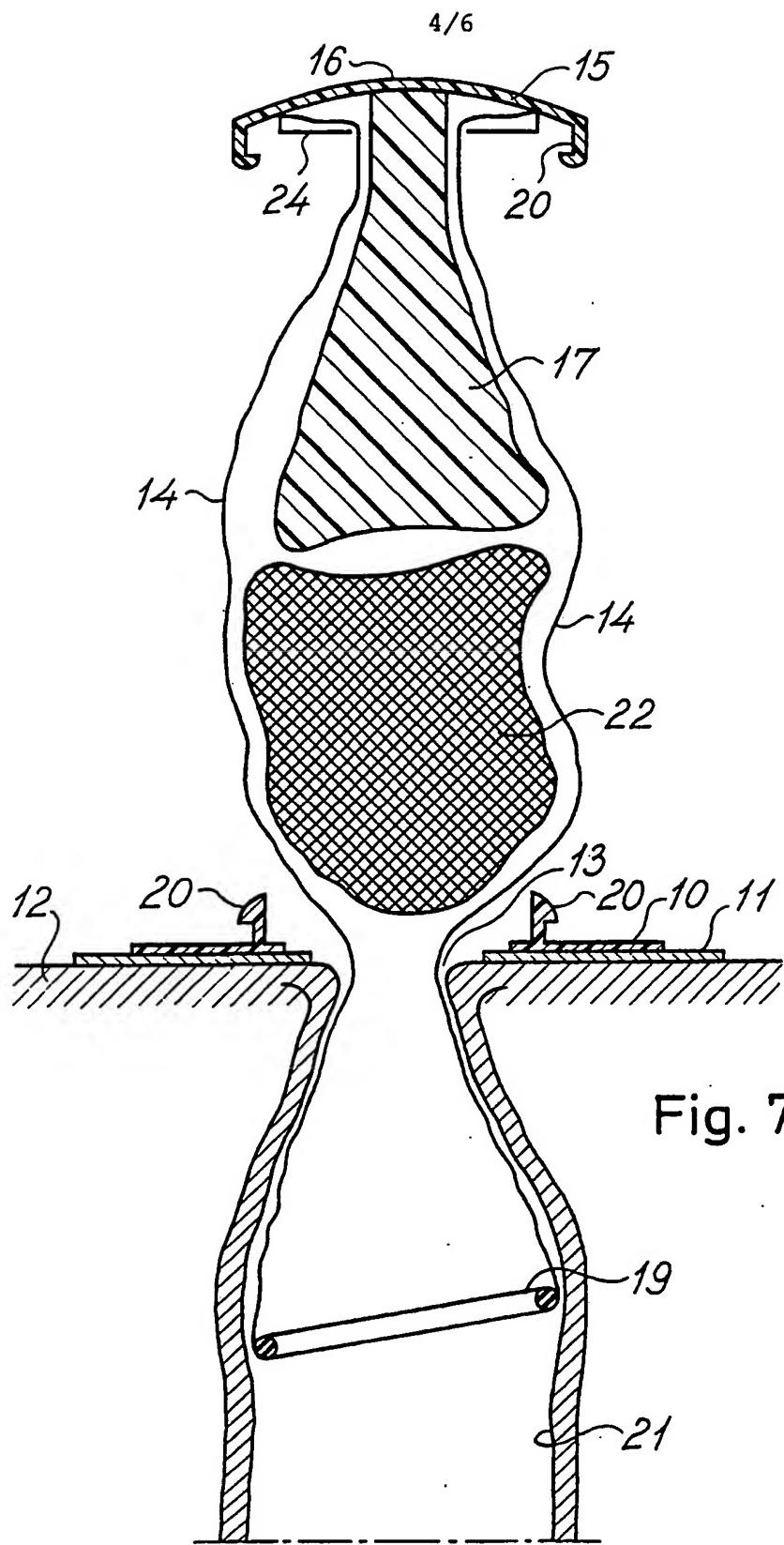


Fig. 7

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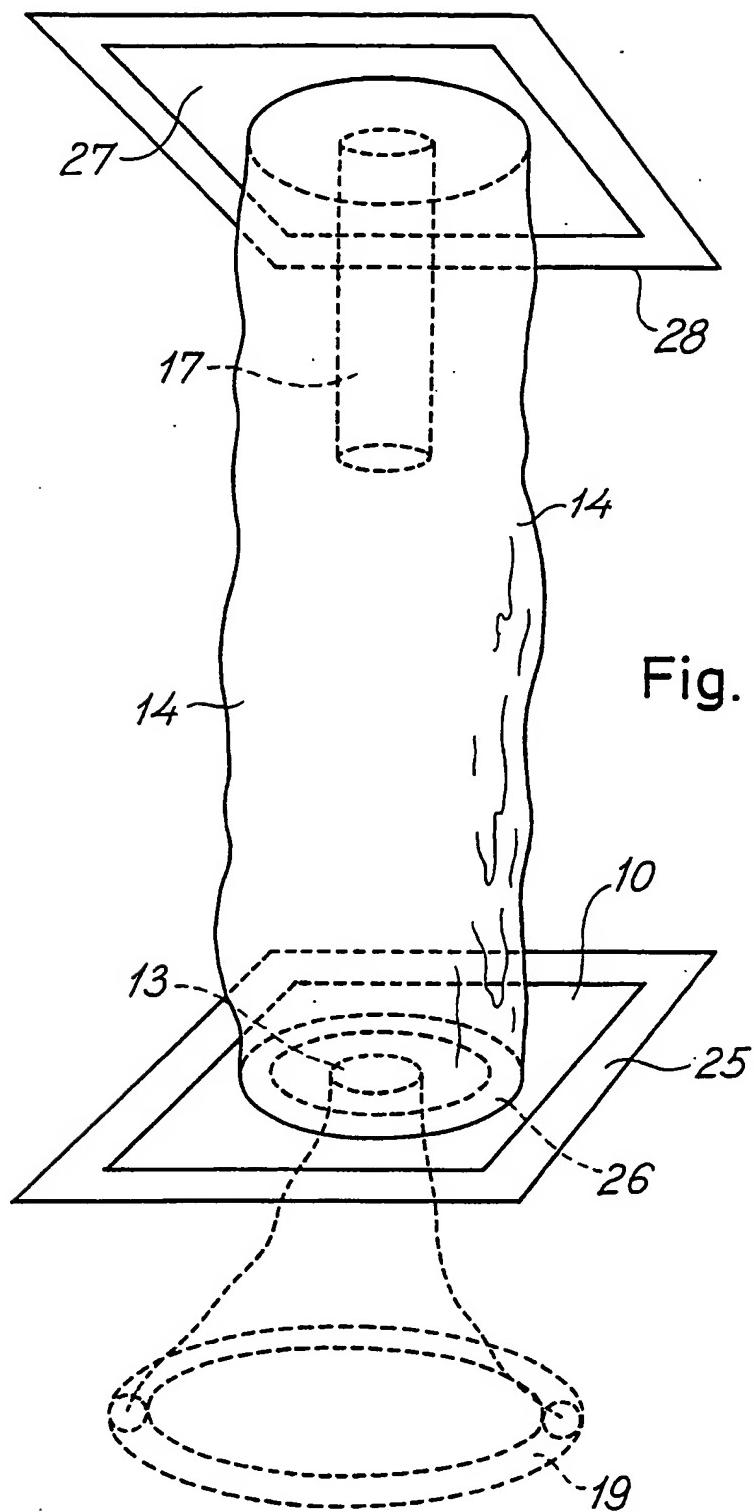


Fig. 8

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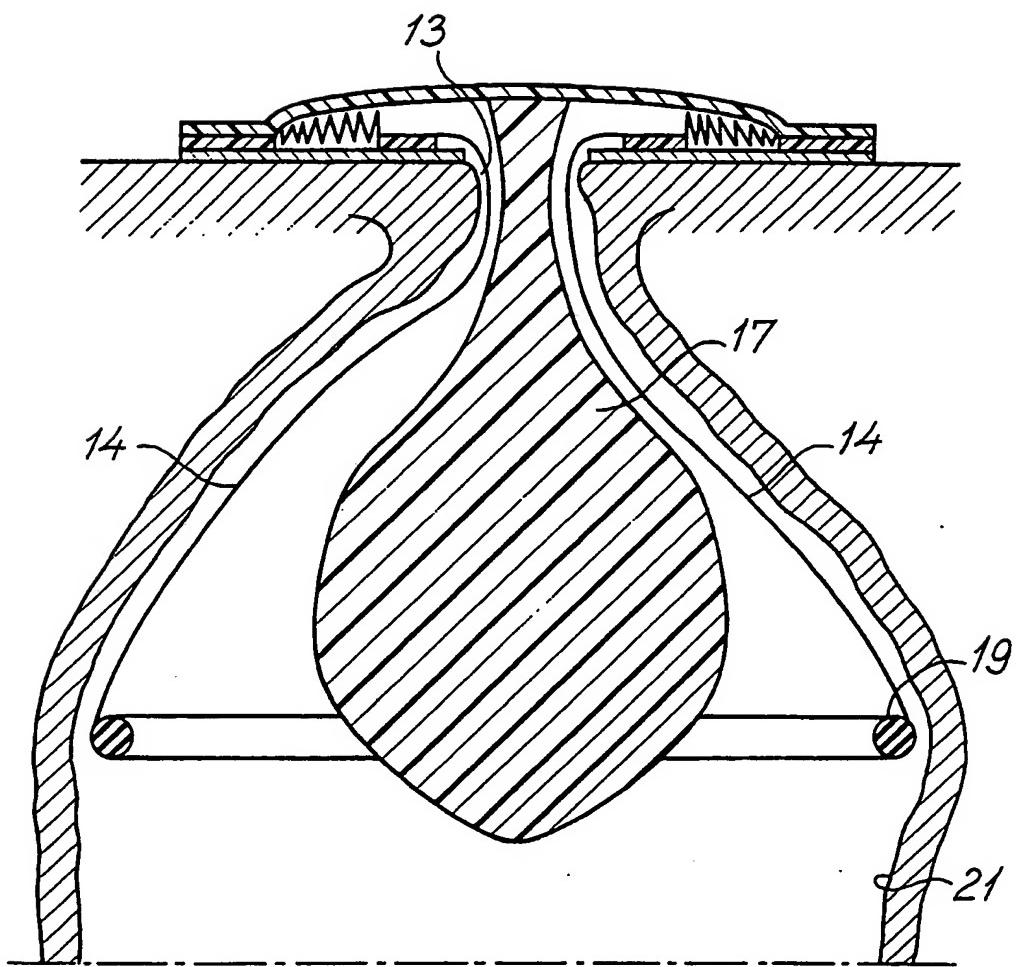


Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No. PCT/DK 90/00003

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 F 5/445

II. FIELDS SEARCHED

Minimum Documentation Searched ?

Classification System	Classification Symbols
IPC5	A 61 F

Documentation Searched other than Minimum Documentation
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SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT*

Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages ***	Relevant to Claim No. 13
X	WO, A1, 87/01274 (TRIMARK (R & D) LIMITED) 12 March 1987, see the whole document --	1-7,9, 11-13
A	DK, B, 153122 (COLOPLAST A/S) 20 June 1988, see the whole document --	
A	DE, A1, 2431888 (KOSS, WALTER) 22 January 1976, see the whole document --	
A	DE, A1, 2811383 (CHEMISCHE FABRIK STOCKHAUSEN & CIE) 27 September 1979, see the whole document --	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search
6th April 1990

Date of Mailing of this International Search Report

1990 -04- 09

International Searching Authority

SWEDISH PATENT OFFICE

Signature of Authorized Officer

Leif Karnsäter *[Signature]*

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	DE, B1, 2919467 (KREFT, WILFRIED ET AL) 9 October 1980, see the whole document ---	
A	US, A, 4067335 (SILVANOV) 10 January 1978, see the whole document -----	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 90/00003**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A1- 87/01274	87-03-12	NONE		
DK-B- 153122	88-06-20	NONE		
DE-A1- 2431888	76-01-22	NONE		
DE-A1- 2811383	79-09-27	JP-A-	54135491	79-10-20
DE-B1- 2919467	80-10-09	NONE		
US-A- 4067335	78-01-10	AT-B- AU-B- AU-D- BE-A- CA-A- CH-A- DE-A-C- FR-A-B- GB-A- JP-A- NL-A- SE-B-C- SE-A-	349622 503463 1105276 838508 1074654 591239 2605802 2300545 1522391 51105195 7601384 417157 7601395	79-04-10 79-09-06 77-08-18 76-05-28 80-04-01 77-09-15 76-08-26 76-09-10 78-08-23 76-09-17 76-08-16 81-03-02 76-08-13

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